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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,943	10/31/2003	Klas Stoltz	STOLTZ11	8947
<div>.1444      7590      10/11/2007 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303</div>			<div>EXAMINER HOEKSTRA, JEFFREY GERBEN</div>	
			<div>ART UNIT 3736</div>	<div>PAPER NUMBER</div>
			<div>MAIL DATE 10/11/2007</div>	<div>DELIVERY MODE PAPER</div>

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/697,943

Applicant(s)

STOLTZ, KLAS

Examiner

Jeffrey G. Hoekstra

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 20-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 20-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 October 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/06/2007 has been entered.

### ***Notice of Amendment***

2. In response to the amendment filed on 08/06/2007, amended claim(s) 1, canceled claim(s) 10-19, and new claim(s) 20-26 is/are acknowledged. The current rejections of the claim(s) 1-9 is/are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 20-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Gu et al. (US 5,971,942, hereinafter Gu).

5. For claim 20, Gu discloses a swallowable, digestive-fluid sampling capsule (the sampler positively recited in the abstract) as best seen in Figures 1-4, comprising:

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- a capsule wall (10) defining at least one inlet opening (20);
- an inner chamber (40) defined by said capsule wall operable effective to hold vacuum or negative pressure relative to the environment, wherein said inlet opening is sealably engaged (abstract); and
- a blocking member (the edges of wall 10) disposed in said inner chamber adjacent to said inlet opening in said capsule wall (as best seen in Figures 2B and 2C),
- wherein said blocking member comprises an elastic material that is operably configured to (a) permit fluid flow of a body substance into said inner chamber as long as a pressure difference exists between said inner chamber and an external environment of the capsule following contact with the body substance and (b) prevent fluid flow through said inlet opening from the inside of the chamber to the exterior environment when said pressure difference has been equalized (column 2 lines 23-33).

6. For claim 21, Gu discloses a swallowable, digestive-fluid sampling capsule, wherein said inlet opening is sealed by a plug member (30) of a material that is dissolved following contact with said body substance (abstract).

7. For claim 25, Gu discloses a swallowable, digestive-fluid sampling capsule, wherein said plug member consists of two or more layers of different dissolvable materials (column 2 lines 13-20).

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-3 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gu in view of Bucalo (US 4,257,427).

10. For claim 1, Gu discloses a swallowable, digestive-fluid sampling capsule (the sampler positively recited in the abstract) as best seen in Figures 1-4, comprising:

- a capsule wall (10) defining at least one inlet opening (20);
- an inner chamber (40) defined by said capsule wall operable effective to hold vacuum or negative pressure relative to the environment, wherein said inlet opening is sealably engaged (abstract); and
- a blocking member (the edges of wall 10) disposed in said inner chamber adjacent to said inlet opening in said capsule wall (as best seen in Figures 2B and 2C),
- wherein said blocking member comprises an elastic material that is operably configured to (a) permit fluid flow of a body substance into said inner chamber as long as a pressure difference exists between said inner chamber and an external environment of the capsule following contact with the body substance and (b) prevent fluid flow through said inlet opening from the inside of the chamber to the exterior environment when said pressure difference has been equalized (column 2 lines 23-33).

11. For claim 2, Gu discloses a swallowable, digestive-fluid sampling capsule, wherein said inlet opening is sealed by a plug member (30) of a material that is dissolved following contact with said body substance (abstract).

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12. For claim 3, Gu discloses a swallowable, digestive-fluid sampling capsule, wherein said blocking member consists of an elastic, operably self-sealing membrane, which in a fluid flow preventing configuration sealingly bears on the inside of said capsule wall effective to prevent an outflow of the body substance in the inner chamber (column 1 lines 6-8 and column 2 lines 23-33).

13. For claim 7, Gu discloses a swallowable, digestive-fluid sampling capsule, wherein said plug member consists of two or more layers of different dissolvable materials (column 2 lines 13-20).

14. Thus for claims 1-3 and 7, Gu discloses the claimed invention except for explicitly disclosing a capsule comprising a capsule wall and an inner chamber with an inlet opening wherein an elastic separate blocking member is disposed within the inner chamber adjacent to and spaced from the inlet opening in the capsule wall.

15. Bucalo discloses a capsule (60) comprising a capsule wall (62,66) and an inner chamber (the interior of 60) with an inlet opening (68) wherein an elastic separate blocking member (70) is disposed within the inner chamber adjacent to and spaced from the inlet opening in the capsule wall (as best seen in at least Figure 5) (column 7 line 43 – column 9 line 23).

16. All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. All of the component parts are known in Gu and Bucalo. The only difference is the combination of the component

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parts into a single device. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the components as taught by Gu with the components as taught by Bucalo to achieve the predictable results of increasing the efficacy of an physiologically-triggered device to automatically obtain and secure samples for diagnosis.

17. Claims 4-6 and 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gu in view of Bucalo and in further view of Pawelec (US 4,481,952).

18. Gu in view of Bucalo discloses the claimed invention, including a bell-shaped blocking member (as best seen in Figures 1-4), except for explicitly disclosing a capsule wherein (a) the capsule comprises two members, a cap member and a body member that are permanently joined to each other and disposing the blocking member therein; (b) the blocking member having at least one laterally located aperture to establish fluid communication of a body substance with said inner chamber; (c) a peripheral edge of said blocking member is disposed between said cap member and said body member; (d) a filter is disposed between said cap member and said body member; and (e) protrusions are externally disposed on said capsule oriented circumferentially with respect to said inlet opening thereby forming inlet grooves.

19. Pawelec discloses a swallowable, digestive-fluid sampling capsule (G), wherein (a) the capsule comprises two members, a cap member (46a) and a body member (46b) that are permanently joined to each other and disposing the blocking member (9) therein; (b) the blocking member having at least one laterally located aperture (16) to

establish fluid communication of a body substance with said inner chamber; (c) a peripheral edge of said blocking member is disposed between said cap member and said body member (as best seen in Figures 12 and 13); (d) a filter (12) is disposed between said cap member and said body member; and (e) protrusions (the enlarged portions of element 14) are externally disposed on said capsule oriented circumferentially with respect to said inlet opening thereby forming inlet grooves (as best seen in Figures 12 and 13).

20. All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. All of the component parts are known in Gu in view of Bucalo and Pawelec. The only difference is the combination of the component parts into a single device. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the components as taught by Gu in view of Bucalo with the components as taught by Pawelec to achieve the predictable results of increasing the efficacy of an physiologically-triggered device to automatically obtain and secure samples for diagnosis.

21. Claims 22-24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gu in view of Pawelec.

22. Gu discloses the claimed invention, including a bell-shaped blocking member (as best seen in Figures 1-4), except for explicitly disclosing a capsule wherein (a) the



capsule comprises two members, a cap member and a body member that are permanently joined to each other and disposing the blocking member therein; (b) the blocking member having at least one laterally located aperture to establish fluid communication of a body substance with said inner chamber; (c) a peripheral edge of said blocking member is disposed between said cap member and said body member; (d) a filter is disposed between said cap member and said body member; and (e) protrusions are externally disposed on said capsule oriented circumferentially with respect to said inlet opening thereby forming inlet grooves.

23. Pawelec discloses a swallowable, digestive-fluid sampling capsule (G), wherein (a) the capsule comprises two members, a cap member (46a) and a body member (46b) that are permanently joined to each other and disposing the blocking member (9) therein; (b) the blocking member having at least one laterally located aperture (16) to establish fluid communication of a body substance with said inner chamber; (c) a peripheral edge of said blocking member is disposed between said cap member and said body member (as best seen in Figures 12 and 13); (d) a filter (12) is disposed between said cap member and said body member; and (e) protrusions (the enlarged portions of element 14) are externally disposed on said capsule oriented circumferentially with respect to said inlet opening thereby forming inlet grooves (as best seen in Figures 12 and 13).

24. All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to

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one of ordinary skill in the art at the time of the invention. All of the component parts are known in Gu and Pawelec. The only difference is the combination of the component parts into a single device. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the components as taught by Gu with the components as taught by Pawelec to achieve the predictable results of increasing the efficacy of an physiologically-triggered device to automatically obtain and secure samples for diagnosis.

***Response to Arguments***

25. Applicant's arguments filed 08/06/2007 with respect to claims 1-9 have been considered but are moot in view of the new ground(s) of rejection.

26. Applicant's arguments filed 08/06/2007 with respect to claims 20-26 have been fully considered but they are not persuasive. Applicant argues claim 20 is clearly not disclosed by Gu, is patentable for the same reasons as claim 1, and incorporates the features of claim 3. The Examiner disagrees, sets forth the rejection under Gu above, and notes the following:

27. Applicants arguments do not appear supported by the claim language of new claim 20. Claim 20 does not positively recite the language of amended claim 1 (e.g. a separate blocking member disposed within the inner chamber adjacent to and spaced from the inlet opening in the capsule wall) nor does it positively recite the subject matter of claim 3 (e.g. a blocking member consisting of an elastic, self-sealing membrane).

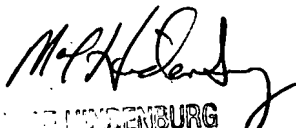
**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J.H./  
Jeff Hoekstra  
Examiner, Art Unit 3736

  
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